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18351 U.S. PTO 112603

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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INVENTOR(S)

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☐ *Additional inventors are being named on the _____ separately numbered sheets attached hereto*

15535 U.S. PTO 60/525626 112603

TITLE OF THE INVENTION (500 characters max)

PERORAL TRANSGASTRIC ENDOSCOPIC LIGATION OF FALLOPIAN TUBES

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ENCLOSED APPLICATION PARTS *(check all that apply)*

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Respectfully submitted, Michael C. Barrett

SIGNATURE _____

Date 11/26/2003

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REGISTRATION NO. *(if appropriate)* 44,523

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PATENT
UTSG:265USP1

Provisional Application For United States Letters Patent

For

PERORAL TRANSGASTRIC ENDOSCOPIC LIGATION OF FALLOPIAN TUBES

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Background of the Invention

1. Field of the Invention

The present invention relates generally to medical techniques and associated devices. More particularly, and in a preferred embodiment, it relates to prevent pregnancy through new surgical techniques and associated devices. Even more particularly, a preferred embodiment concerns peroral transgastric endoscopic ligation of fallopian tubes.

2. Description of Related Art

Traditionally, access to the peritoneal cavity (for, *e.g.*, ligation of fallopian tubes) involves abdominal incisions, laparoscopic or otherwise. However, incision of the skin, subcutaneous fat tissue, and/or abdominal wall muscle can cause numerous potential complications including but not limited to infection, formation of abscess, post-operative hernias.

It would therefore be advantageous to provide access to the peritoneal cavity without the need for any abdominal incisions, laparoscopic or otherwise.

Referenced shortcomings of conventional methodologies mentioned above are not intended to be exhaustive, but rather are among many that tend to impair the effectiveness of previously known techniques concerning access to peritoneal cavities and, more specifically, access required for ligation of fallopian tubes. Other noteworthy problems may also exist; however, those mentioned here are sufficient to demonstrate that methodology appearing in the art have not been altogether satisfactory and that a significant need exists for the techniques described here.

Summary of the Invention

Shortcomings of the prior art are reduced or eliminated by the techniques disclosed here. These techniques are applicable to a vast number of applications, including but not limited to a preferred application involving ligation of fallopian tubes.

In a broad respect, a preferred embodiment concerns a technique of ligation of the fallopian tubes as a method to prevent pregnancy. The technique involves peroral transgastric access to the peritoneal cavity, with localization of the fallopian tubes with application of a ligature with or without subsequent severing of the tubes by cautery or other techniques.

Advantageously, this technique provides peroral transgastric access to the peritoneal cavity without the need for any abdominal incisions, laparoscopic or otherwise.

A large variety of endoscopic accessories can be designed and/or modified for this use, as will be apparent to those having ordinary skill in the art.

In one embodiment, the invention involves a method for ligation of fallopian tubes. An endoscope is used to orally access a gastric wall. The gastric wall is punctured to provide access to a peritoneal cavity. The endoscope is advanced into the peritoneal cavity through the puncture. A fallopian tube is located and ligated. The endoscope is removed, and the puncture is sealed. Puncturing the gastric wall may include puncturing with an endoscopic balloon, which is inflated to provide access to the peritoneal cavity. Puncturing the gastric wall may include puncturing with a needle knife electrocautery followed by balloon dilatation with a dilating balloon.

In one embodiment, the invention involves a method of preventing pregnancy comprising peroral transgastric endoscopic ligation of fallopian tubes.

In one embodiment, the invention involves an apparatus configured for peroral transgastric endoscopic ligation of fallopian tubes.

In one embodiment, the invention involves an apparatus for peroral transgastric endoscopic ligation of fallopian tubes. The apparatus includes an endoscope adapted to orally access a gastric wall and an endoscopic balloon configured to puncture the gastric wall and to provide access into a peritoneal cavity upon inflation. It can also include endoscopic forceps adapted to grasp a fallopian tube. It can also include a loop configured to block a patency of the fallopian tube.

In one embodiment, the invention involves an apparatus for peroral transgastric endoscopic ligation of fallopian tubes, which includes an endoscope adapted to orally access a gastric wall, a needle knife electrocautery configured to puncture the gastric wall, and a dilating balloon configured to expand the puncture to provide access into a peritoneal cavity. It can also include endoscopic forceps adapted to grasp a fallopian tube. It can also include a loop configured to block a patency of the fallopian tube.

Other features and associated advantages will become apparent with reference to the following detailed description of specific embodiments along with the accompanying examples.

Description of Illustrative Embodiments

Embodiments of this invention can be used in humans for sterilization to prevent unwanted pregnancy. Comparing to existing techniques of surgical or laparoscopic tubal ligation, those embodiments can eliminate incision of the skin, subcutaneous fat tissue and abdominal wall muscle, preventing numerous potential complications including but not limited to: formation of abscess, post-operative hernias.

In a general embodiment, an upper endoscopy is performed under general anesthesia using sterile technique and equipment. The gastric wall is punctured with an endoscopic balloon or other device suitable to make a puncture and to provide access. If a balloon is used, it is inflated to provide access into the peritoneal cavity. The endoscope is then advanced into the peritoneal cavity. A fallopian tube is located. The tube can be grasped with endoscopic forceps and detachable sterilized Endoloop® applied to the tube to block its patency. The endoscope is then be removed, and the gastric wall opening is closed.

Those having ordinary skill in the art will recognize, with the benefit of this disclosure that other embodiments relating to the general embodiment described above can be used to likewise provide access to, and perform procedures on associated structures in, the peritoneal cavity.

Additionally, with the benefit of the present disclosure, those having ordinary skill in the art will comprehend that techniques described here may be modified and applied to a number of additional, different applications, achieving the same or a similar result. The attached claims cover all such modifications that fall within the scope and spirit of this disclosure.

* * *

The following examples are included to demonstrate specific embodiments of this disclosure. It should be appreciated by those of skill in the art that the techniques disclosed in the examples represent techniques discovered by the inventors to function well in the practice of the invention, and thus can be considered to constitute specific modes for its practice. However, those of ordinary skill in the art should, in light of the present disclosure, appreciate that many changes can be made in the specific embodiments which are disclosed and still obtain a like or similar result without departing from the spirit and scope of the invention.

Examples

Per-Oral Transgastric Endoscopic Ligation of Fallopian Tubes with Long-Term Survival in a Porcine Model

Background

The inventors have previously reported the safety and feasibility of the per-oral transgastric endoscopic approach for various interventions on intra-abdominal organs (diagnostic peritoneoscopy, liver biopsy, gastrojejunostomy). This approach eliminates incision of abdominal wall providing an alternate approach to diagnostic and therapeutic laparoscopy. This example reports the successful performance of per-oral endoscopic transgastric ligation of fallopian tubes.

Methods

Five 50Kg pigs had general anesthesia and irrigation of the stomach with antibiotic solution. Gastric puncture was performed with a prototype needle knife electrocautery (Olympus®) followed by balloon dilatation of the tract with a biliary dilating balloon (Microvasive). A standard upper endoscope that had high level disinfection followed by gas sterilization and was advanced into the peritoneal cavity. Both Fallopian Tubes were identified and one of them was ligated using Olympus

Endoloop® with the other serving as a control. Tubal patency was evaluated by hysterosalpingogram in all pigs before and after ligation. All pigs were survived for 1-3 weeks then sacrificed for postmortem examination.

Results

Uterine tubes were easily identified and ligated in all 5 pigs. In each pig fluoroscopy confirmed complete obstruction of ligated tube with preserved patency of the opposite tube. All pigs survived well and ate heartily without any ill-effects. Postmortem examination did not reveal any peritonitis or intraabdominal adhesions. The Endoloops® were in place with complete obstruction of the ligated tubes.

Conclusion

The endoscopic transgastric approach provides effective ligation of the fallopian tubes in accordance with long-term survival. The endoscopic transgastric approach to the peritoneal cavity may be used in a wide array of diagnostic and therapeutic procedures.

* * *

References

Each of the following references is incorporated by reference in its entirety:

1. Kalloo AN, Kantsevoy SV, Singh VK, Magee CA, Vaughn CA, Hill SL. Flexible transgastric peritoneoscopy: a novel approach to diagnostic and therapeutic interventions in the peritoneal cavity. Gastroenterology 2000; 118:A1039.
2. Gandhi SG, Komenaka IK, Naim JH. Fitz-Hugh-Curtis syndrome after laparoscopic tubal ligation. A case report. J Reprod Med 2003; 48:302-5.
3. Semm K. [Endoscopic intraabdominal surgery in gynecology]. Wien Klin Wochenschr 1983; 95:353-67.
4. Chiou CF, Trussell J, Reyes E, et al. Economic analysis of contraceptives for women. Contraception 2003; 68:3-10.

Claims:

1. A method for ligation of fallopian tubes, comprising:
using an endoscope to orally access a gastric wall;
puncturing the gastric wall to provide access to a peritoneal cavity;
advancing the endoscope into the peritoneal cavity through the puncture;
locating a fallopian tube;
ligating the fallopian tube;
removing the endoscope; and
sealing the puncture.

2. The method of claim 1, where puncturing the gastric wall comprises puncturing with an endoscopic balloon, which is inflated to provide access to the peritoneal cavity.

3. The method of claim 1, where puncturing the gastric wall comprises puncturing with a needle knife electrocautery followed by balloon dilatation with a dilating balloon.

4. A method of preventing pregnancy comprising peroral transgastric endoscopic ligation of fallopian tubes.

5. An apparatus configured for peroral transgastric endoscopic ligation of fallopian tubes.

6. An apparatus for peroral transgastric endoscopic ligation of fallopian tubes, comprising:

an endoscope adapted to orally access a gastric wall;

an endoscopic balloon configured to puncture the gastric wall and to provide access into a peritoneal cavity upon inflation;

endoscopic forceps adapted to grasp a fallopian tube; and

a loop configured to block a patency of the fallopian tube.

7. An apparatus for peroral transgastric endoscopic ligation of fallopian tubes, comprising:

an endoscope adapted to orally access a gastric wall;

a needle knife electrocautery configured to puncture the gastric wall;

a dilating balloon configured to expand the puncture to provide access into a peritoneal cavity;

endoscopic forceps adapted to grasp a fallopian tube; and

a loop configured to block a patency of the fallopian tube.

Abstract of the Disclosure

Methods and apparatus for accessing the peritoneal cavity and for ligation of fallopian tubes. A representative method includes using an endoscope to orally access a gastric wall. The gastric wall is punctured to provide access to a peritoneal cavity. The endoscope is advanced into the peritoneal cavity through the puncture. A fallopian tube is located and ligated. The endoscope is removed, and the puncture is sealed.